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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,488	11/20/2003	Richard W. Armentrout	850136.422	3667

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EXAMINER	
FERNANDEZ, SUSAN EMILY	

ART UNIT	PAPER NUMBER
1651	

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09/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,488	ARMENTROUT, RICHARD W.	
	Examiner	Art Unit	
	Susan E. Fernandez	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed May 16, 2007, has been received and entered.

Claims 16 and 17 are pending and are examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole (BioTechniques. 26: 748-756, April 1999) in view of Coen et al. ("The Polymerase Chain Reaction," in Ausubel et al., (eds.), Current Protocols in Molecular Biology, John Wiley & Sons, Inc., Chapter 15, Sections 1-8, 2003.).

Cole discloses gellan electrophoresis gels for the separation and isolation of DNA (abstract). The gellan electrophoresis gels of concentrations as low as 0.03% were prepared, but a typical gellan electrophoresis gel concentration was 0.1% (page 750, second column).

Cole differs from the claimed invention in that it does not recite that the gellan electrophoresis gel comprises DNA polymerase, dNTPs, and a target nucleic acid.

Coen et al. discloses that the first step of PCR requires the mixing of template DNA (target nucleic acid), DNA polymerases, and dNTPs, among a few other components (page 15.1.1, first paragraph). Afterwards, the PCR products are displayed on an appropriate gel and examined for yield and specificity (page 15.1.1., first paragraph).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used the Cole gellan electrophoresis gel as the gel for displaying the PCR products of a PCR reaction, and in doing so, the resulting gel further comprises the PCR products (amplified DNA, target nucleic acid, DNA polymerase, dNTPs). One of ordinary skill in the art would have been motivated to do this since gellan gum serves as an alternative gel material which allows for easy recovery of DNA (page 756, last paragraph), requires low concentrations for gel formation, and has reversibility (page 749, first column, second paragraph). Thus, recovery of PCR DNA products could be more easily performed, and is in contrast to the recovery of PCR DNA products from agarose gel, wherein a commercial device must be used to nebulize the gel and filter out the gel particles using an ultrafilter (Cole, page 748, third column, first paragraph).

Note that in instant claim 17, the recitation of "template-dependent nucleic acid amplification is of enhanced sensitivity" indicates the intended use of the composition. As pointed out in MPEP §2112, "the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable." Furthermore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed May 16, 2007, have been fully considered but they are not persuasive. Applicant asserts that the person of ordinary skill in the art would not have predicted that PCR can proceed in the presence of gellan. Applicant points to support in the disclosure which states that gellan sequesters Mg^{2+} in the course of gel formation. Though the citation (page 14, lines 13-24) fails to indicate this, support is found on page 5, line 25 through page 6, line 6 in the specification. It is respectfully noted that the disclosure and the Doner reference (Biotechnology Techniques. 1991. 5(1): 25-28, listed on IDS) speak to the sequestration of magnesium ions during gellan gel formation, and not during processes wherein the gellan gel in its final form is used. It is noted that magnesium chloride concentration is critical for the outcome of PCR and that magnesium chloride is added to aliquots (Coen et al., page 15.1.1, second paragraph) which are cycled and then displayed on gel (Coen et al., page 15.1.2, second-to-last paragraph through page 15.1.3, last paragraph). Clearly the magnesium ion concentration present in the aliquots, and not in the electrophoresis gel, affect PCR. Moreover, since the prior art does not speak to magnesium ion sequestration during use of gellan gel, there is no teaching away from using gellan for electrophoresis of PCR products. Thus, gellan is also considered an appropriate electrophoretic medium which does not interfere with the intended use of DNA.

Applicant asserts that no evidence or reasoning had been provided as to why the person of ordinary skill in the art would have been motivated to use the Cole gellan electrophoresis gel for displaying PCR products. However, it is noted in the previous office action that motivation is found in Cole which teaches that gellan gum serves as an alternative gel material which allows

for easy recovery of DNA, requires low concentrations for gel formation, and has reversibility. Specifically, Cole states that "...gellan gum offers an alternative gel material that has some unique properties. The conditions for the recovery of DNA are mild and easily accomplished" (page 756, last paragraph). For these reasons, one of ordinary skill in the art would have been motivated to have used the Cole gellan electrophoresis gel as the gel for displaying the PCR products of a PCR reaction. In doing so, the composition comprising the gellan gum and the PCR products is considered a "composition suitable for use in nucleic acid amplification" since it is used as a final step in PCR, a nucleic acid amplification process. The pending claims do not expressly state that the composition is a nucleic acid amplification reaction mixture, wherein a reaction is occurring.

The applicant also points to a specific passage in Cole (page 750, left-hand column, last paragraph) to show that Cole teaches that the use of divalent cations in gellan gum can hinder gel preparation. However, it is respectfully noted that this passage in Cole indicates that the detrimental effects of divalent cations on gellan gum occurs only when not all of the gellan gum particles are in solution. A suitable gellan gum can be prepared using divalent cations as long as care is taken to ensure that all of the gellan gum particles are in solution before adding the divalent cation. Moreover, this passage speaks to the weakening of gellan gum by divalent cations when gellan gel is being prepared, and not to the effects of divalent cation on a formed gellan gel. Therefore, the person of ordinary skill in the art would not have arrived at any conclusions regarding any detrimental effects of PCR products comprising magnesium ions on a gellan gel when the PCR products are displayed on the gel. With respect to the arguments regarding gellan gels formed using diamines, as the person of ordinary skill would have still been

motivated to use a gellan gel formed using divalent cations, the person of ordinary skill in the art would not necessarily resort to using the gellan gums formed using diamines, which in turn avoids the pH incompatibility issues argued by the applicant.

Finally, it is noted that KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396).

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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sef